



ANALYTICAL RESEARCH LABORATORIES

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Microbiology Report

CLIENT: New England Compounding Center
697 Waverly Street
Framingham, MA 01702

ARL #: 185744-01

LOT #: 08272012@87

DESCRIPTION: Polymyxin/ Bacitracin *Winchester* 1MU-50KU/20mL Solution

DATE RECEIVED: 08/28/2012

STORAGE: 2°C to 8°C (35.6°F to 46.4°F)

CONTAINER: Two 3 mL syringes

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility (*Preliminary*)	Sterile / Not Sterile	No Growth at 3 Days	USP 71	08/28/2012
Endotoxin	No USP Limit	<4.00 EU/mL	USP 85	08/30/2012

Amar Arafat - Microbiologist

Got 08/31/12

08/31/2012

Date Reported

Sterility – This preliminary report was issued after approximately 72 hours of incubation. In accordance with the USP guidelines, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Fungal – This preliminary report was issued after approximately 4 days of incubation. In accordance with the USP guidelines, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Endotoxin - To calculate the endotoxin limit use the following formulae: $EL = K/M$ where K = tolerance limit (EU/kg) and M = Maximum dose/kg/hour or Maximum dose/kg

Parenteral: K is 5 EU/kg for any route of administration /Intrathecal: K is 0.2 EU/kg body weight)

Radiopharmaceutical parenteral: K is $175/V$ or Intrathecal radiopharmaceuticals: K is $14/V$, where V is the maximum recommended dose in mL.

Dermal Application: K/M , where K = 5 EU/kg and M is the (maximum dose/m²/hour × 1.80 m²)/70 Kg.

Results reported above relate only to the sample that was tested.